PCT/GB 2004 / 0 0 1 3 9 0

INVESTOR IN PEOPLE

The Patent Office
Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

RECD 10 MAY 2004
WIPO PCT

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

I also certify that the application is now proceeding in the name as identified herein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.

Signed Andrew Gerry

Dated 30 April 2004

PRIORITY DOCUMENT

SUBMITTED OR TRANSMITTED IN COMPLIANCE WITH RULE 17.1(a) OR (b)

GB 0307082.8

By virtue of a direction given under Section 30 of the Patents Act 1977, the application is proceeding in the name of:

MPATHY MEDICAL DEVICES LIMITED,
6.05 Kelvin Campus,
West of Scotland Science Park,
GLASGOW,
G20 0SP,
United Kingdom

Incorporated in the United Kingdom,

[ADP No. 08730905001]

THE PATENT OFFICE
CD
27 MAR 2003
RECEIVED BY FAX

Patents Form 1/77

Patents Act 1977
(Rule 16)

27MAR03 E795753-1 D02884
P01/7700 0.00-0307082.8

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office

Cardiff Road
Newport
South Wales
NP10 8QQ

1. Your reference — P29925-/CMU/RTH/RMC

2. Patent application number *(The Patent Office will fill in this part)* — 0307082.8 — 27 MAR 2003

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

Gyne Ideas Limited
1 Bell Leys
Wingrave
Buckinghamshire HP22 4QS
United Kingdom

4/3/04

Patents ADP number *(if you know it)*

SECTION 8 (1977 ACT) APPLICATION FILED 8246420001

If the applicant is a corporate body, give the country/state of its incorporation — United Kingdom

4. Title of the invention — "Drug Delivery Device and Method"

5. Name of your agent *(if you have one)* — Murgitroyd & Company

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

Scotland House
165-169 Scotland Street
Glasgow
G5 8PL

Patents ADP number *(if you know it)* — 1198018

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

Yes

Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	
Description	26
Claim (s)	-
Abstract	-
Drawing (s)	5

10. If you are also filing any of the following, state how many against each item.

Priority documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patents Form 9/77)*	
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature Murgitroyd & Company Date 27 March 2003

Murgitroyd & Company

12. Name and daytime telephone number of person to contact in the United Kingdom: ROISIN MCNALLY 0141 307 8400

Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

a) If you need help to fill in this form or you have any questions, please contact the Patent Office on 08459 500505.

b) Write your answers in capital letters using black ink or you may type them.

c) If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.

d) If you have answered 'Yes' Patents Form 7/77 will need to be filed.

e) Once you have filled in the form you must remember to sign and date it.

f) For details of the fee and ways to pay please contact the Patent Office.

"Drug Delivery Device and Method"

This invention relates to a drug delivery device and a method of delivering a drug.

There is a huge number of drugs which may be administered to the human and animal body for the prevention or treatment of disease. Different types of drugs call for different ways of administering the drug to the human or animal body.

Perhaps the most common method of delivering a drug is by ingestion. In other words, drugs are provided in pill, capsule, powder or liquid form for oral administration to a human or animal. The drug is then absorbed by the digestive system and will usually enter the blood stream via the liver to take effect. However, far from all drugs are suitable for such administration. For example, many drugs would be broken down by the digestion process and destroyed before they can enter the blood stream. This problem is caused by what is commonly referred to as the "first past liver metabolism" of the human

or animal body, i.e. the process by which all substances absorbed by the digestive system must pass through the liver into the blood stream.

Another very common way in which drugs are administered, which avoids the problems of the first past liver metabolism, is by injection. Drugs desired to take an instant effect in the blood stream of a human or animal body may be injected into a vein, i.e. intravenously. Alternatively, drugs may be injected into muscle tissue from which the drug is absorbed more slowly into the blood stream. Drugs for injection into muscle tissue may, for example, be provided in an oily base which helps to regulate the rate of absorption. However, injections can be painful and difficult, particularly injections into muscle tissue, and can lead to tissue damage where frequent injections are required on a long term basis, e.g. of insulin for diabetics. Other types of drug delivery include nasal sprays for administration of drugs to the nasal tissues and lungs; patches, such as the Nicorette® patch, for the application of drugs, e.g. Nicotine, through the skin; and lotions or ointments for topical application, i.e. directly to an affected part of the body.

All of the above drug delivery methods are useful for particular types of drugs and medicines, but are unable to provide therapeutic levels of drugs over a long term, e.g. weeks and months rather than days,

without repeated application by the patient or a carer.

For passive application of drugs on a long term basis, various implants have been developed. One such type of implant may be inserted under the skin and have a mechanism for slowly releasing a drug into the blood stream of the human or animal in which it is implanted. For example, Norplant® or Implanon® comprise an implant having small capsules or rods which slowly release levonorgestrel or etonorgestrel into the blood stream to provide a contraceptive effect for women. Norplant® can be effective for up to five years. However, the insertion of such an implant is painful and requires local anaesthesia on both insertion and removal. Furthermore, implantation can cause significant bruising and discomfort. In addition, as such implants are placed under the skin in for example the arm, they can be visible and cause discolouration of the skin. As the arm contains many different types of tissue and planes of tissue, movement of the implant along or through these tissue planes can occur. This can mean the implant moves to locations other than where it was placed during insertion which can lead to complications for the patient, in particular during removal of the implant. Difficulties with the Norplant® implant has led to it being withdrawn from clinical use.

Another type of implant is a contraceptive coil or intrauterine device, IUD or IUCD which is placed in

the uterus to provide a contraceptive effect. A coil may be impregnated with hormones such as levonorgestrel to reduce the thickening of the endometrium of the uterus during the menstrual cycle. Likewise vaginal rings, comprising soft plastic rings of around 4cm to 5cm in diameter impregnated with a desired drug, are sometimes used for hormone replacement therapy. Vaginal rings are placed in the vagina around the cervix where they can slowly release a drug into the bloodstream through the soft tissue of the cervix. However, such vaginal rings are uncomfortable during sex and both vaginal rings and coils can lead to vaginal discharges and general discomfort to the wearer. Coils in particular can cause severe discomfort, such as stomach cramps, due to the direct application of levonorgestrel to the uterus.

According to the present invention there is provided a drug delivery device comprising an implant for insertion into the myometrium (the smooth muscle of the uterus).

In one embodiment the implant comprises a point to facilitate insertion into the myometrium and a body in which a drug can be held prior to delivery.

The implant may further comprise insertion and / or retrieval means to allow manipulation. This is advantageous over implants previously known in the art as the myometrium has few somatic (pain) nerves. Further there is little tissue or muscle movement in

the myometrium compared with for example the tissues of the arm or the leg. In addition, the myometrium does not comprises as many layers or planes of tissue as in the arm or leg, minimising the liklihood of movement of the implant following insertion to a different location.

There is also provided a method of delivering a drug comprising inserting at least one drug delivery device into the myometrium.

The myometrium is the smooth muscle of the body of the uterus and the cervix.

Preferably the drug delivery device is an implant which can be inserted into the myometrium, for retention therein.

Preferably the drug delivery device is an implant which can be inserted into the myometrium, for retention therein for a defined period of time.

The retention of the implant in the myometrium for a defined period of time allows the delivery of a drug to the surrounding tissues and bloodstream over a period of time.

Preferably access to the myometrium is via the vagina through the cervix. This has the advantage that the implant can be suitably located using a speculum in an outpatient setting. The insertion of the implant in the myometrium would be similar in

both the time taken and the discomfort to the patient as the taking of a smear.

Preferably the implant is located in the myometrium of the cervix. Vaginal access allows the implant to be located in the myometrium of the cervix and the location of the implant can be checked by speculum examination following implantation.

Alternatively access to the myometrium may be available during open or laproscopic surgery. This has the advantage of allowing the implant to be placed at any suitable location in the myometrium, usually of the body of the uterus. The implant may thus be placed in the myometrium of the body of the uterus, or other positions which would not be accessible by access via the vagina.

According to another aspect of the present invention there is provided a drug delivery device comprising an implant for insertion into the prostate gland.

There is also provided a method of delivering a drug comprising inserting at least one drug delivery device into the prostate gland.

Preferably the drug delivery device is an implant which can be inserted into the prostate for retention therein.

This has the advantage that drugs can be delivered to the tissue of the prostate, surrounding the

prostate, and the bloodstream. Further, delivery of drugs directly to the prostate means the drugs are not subjected to liver metabolism as would be the case for drugs provided orally.

Preferably the drug delivery device is an implant which can be inserted into the prostate for retention therein for a defined period of time.

This has the advantage that drugs can be supplied to the tissue of the prostate, the tissue surrounding the prostate, and the bloodstream over a period of time.

Preferably the defined period of time is between 1 month and 5 years from insertion of the implant.

In other words, in one embodiment a drug delivery device is implanted in the myometrium where it releases a drug for absorption through the smooth muscle and soft tissue into the blood stream.

Alternatively, a drug delivery device is implanted in the prostate where it releases a drug for absorption into the blood stream.

The drug delivery device of the present invention differs from the coil or a vaginal ring as disclosed in the prior art, in that the drug delivery device is actively inserted into the tissue of the myometrium. The coil is located in the cavity of the uterus (endometrium) and vaginal rings are

placed at the top of the vagina around the cervix. These devices of the prior art therefore differ from the delivery device of the present invention which is actively inserted into the smooth muscle of the cervix or of the uterine body (myometrium).

Preferably the implant comprises an insertion point and a body including a drug carrying medium which includes the drug to be administered.

The drug is therefore administered by release from the medium, e.g. by the medium dissolving.

Preferably the body is retrievable at the end of the drug application, e.g. after a few weeks, months or years. This has the advantage that the drug delivery means are not left in the body forever and further provides a means for controlling the amount of drug given and the time over which the drug is provided. It can also be removed if the patient requests for any reason or if problems are encountered.

The body may be any material which is capable of providing a semi-sharp point.

Preferably at least the insertion point is metallic.

The myometrium surrounding the uterus and vaginal cavity has very few or no somatic sensory (pain) nerves and insertion and retention of the implant in

this smooth muscle and tissue is therefore substantially painless for the patient or wearer.

This has significant advantages over conventional implants such as Norplant® which are inserted under the skin. Unlike these conventional implants which are inserted into the skin, which has sensory nerves and into which insertion is painful, the implant described by the present invention is inserted into tissues which have minimal numbers of sensory nerves. In addition the minimal number of sensory nerves in the myometrium means that withdrawal of the implant is substantially painless and the presence of the implant during use is not painful and minimal discomfort is experienced by the patient. In effect the implant is "invisible" to the patient, but visible to the clinician if required.

The location of the implant within the smooth muscle of the cervix and uterus provides a novel means of drug delivery to a specific location in the body. The location of the implant promotes rapid absorption of released drug and the released drug does not require to undergo liver metabolism. In addition, drug delivery by means located within the tissue of the myometrium minimises problems of absorption through mucosal layers overlying tissues, as experienced in drug delivery means placed around tissues or in cavities such as vaginal rings and intrauterine devices.

Preferably, the drug delivery device of the present invention is significantly smaller than coils, IUD or vaginal rings. This is advantageous as there will be less discomfort to the person in which the drug delivery device is implanted and less likelihood of rejection of the implant by the body or responses such as inflammation.

The drug delivery device of the present invention is inserted in and retained in the smooth muscle of the myometrium. This differs from the location of intrauterine devices and vaginal rings which are not inserted into tissue or smooth muscle, but instead are placed within the cavity of the uterus or in the vaginal cavity around and not within the tissue of the cervix.

Preferably the implant does not therefore cause any discomfort to the wearer during use.

Another advantage of the present invention is that insertion of the implant into the myometrium provides efficient absorption of the drug. The vaginal cavity is lined or covered with mucus, i.e. vaginal mucosa. Drugs released from a vaginal ring must pass through the vaginal mucosa before being absorbed into the vaginal wall and passing into the blood stream. In contrast, as the implant of the present invention is located in the myometrium, drugs released from the implant pass directly into the smooth muscle and blood stream. This is advantagous as it provides for systemic delivery of

drugs which unlike drugs provided orally do not require to undergo liver metabolism on entry into the body.

The myometrium has a high density of blood vessels and is therefore particularly suited to absorbing drugs released from the implant. The myometrium is also in a convenient location, at the top of the vaginal cavity, for insertion and removal of the implant. This is advantageous as it allows the implant to be placed by vaginal access in an outpatient setting. Further, the location of the implant can be easily checked by speculum examination.

Preferably the implant is inserted and retained in the smooth muscle tissue of the cervix.

Preferably the implant is inserted into the smooth muscle of the cervix via the vagina.

Alternatively the implant is inserted into the myometrium through serosa surrounding the myometrium.

In a further alternative the implant is inserted into the myometrium through the transendometrium.

The prostate is a gland in males which surrounds the top of the bladder.

Preferably insertion of an implant into the prostate is by a transrectal route.

Alternatively the implant can be inserted into the prostate by a trans perineal route.

Preferably insertion of an implant is performed using ultrasound.

As mentioned above, the implant may comprise a body and drug delivery means. More specifically, the implant may comprise a metallic, e.g. surgical steel, body.

Preferably the body comprises a first end which includes a semi-sharp point, a middle portion which provides for drug delivery and retrieval means at second opposite end of the body. It is advantageous if the retrieval means allow the location of the body to be determined by either visual or physical examination.

The body can be of any shape which allows implantation.

Preferably the body is elongate. This allows the implant to be easily inserted into the tissue.

In cross section the body can be of any preferred shape to influence the drug delivery characteristics of the implant. For example the body may be cross

shaped to increase the surface area of the body exposed to the surrounding tissue.

Preferably the body has maximal surface area in relation to its length or volume. This has the advantage of providing maximal absorption of the drug into the surrounding tissues and / or smooth muscle.

Preferably along the length of the body is at least one drug delivery means.

Preferably the drug delivery means comprises a medium carried by the body, in which medium the drug to be administered is carried.

Alternatively, the implant may be a homogeneous unit. For example the body may be formed from the medium carrying the drug. The medium carrying the drug may be absorbable.

In one embodiment the implant is non-absorbable.

Alternatively the implant is at least partially absorbable.

The medium carrying the drug may be enclosed by the body.

Alternatively the medium carrying the drug is not enclosed by the body.

The implant itself may be the medium in which the drug to be administered is carried. In this example, the implant can be soluble. The entire implant can therefore be absorbed over the period of time that the drug is administered.

The implant may have any structure suitable for insertion and retention in the smooth muscle of the myometrium or the tissue of the prostate. For example the implant may comprise barbed portions or surface patterns to promote retention of the implant in the myometrium or prostate. This may be advantageous if movement of the tissue in which the implant is inserted is likely to cause the implant to work loose and move from its intended position.

Preferably, the implant is generally needle shaped or the implant is a needle.

Alternatively the implant comprises a pointed metal spiral attached to means which allows the implant to be moved into the myometrium or the prostate.

The means which allow the implant to be moved into the myometrium or the prostate may also allow the removal of the implant from the myometrium or the prostate.

Preferably the implant is corkscrew shaped.

Preferably the implant has a point at one (distal) end for aiding insertion of the implant into the

myometrium or the prostate. This is advantageous as it allows the implant to be easily inserted into the smooth muscle of the myometrium or the tissue of the prostate. The implant can therefore be pressed into the myometrium using the pointed distal end.

Alternatively, an insertion tool is provided having a pointed end for driving the implant into the myometrium or the prostate. This is advantageous as it means the implant to be left in the body does not require a pointed portion.

According to another aspect of the present invention, there is provided a tool for inserting a drug delivery implant into the myometrium or the prostate, the tool comprising a pointed end for penetrating the smooth muscle and soft tissue and a collar for releasably retaining the implant.

The implant need not have an integral pointed portion.

Preferably the implant is provided in an insertion tool the collar of the tool releasably retaining the implant in the tool while the implant is driven into the myometrium or the prostate using the tool. The implant can then be released from the tool when the implant is suitably located in its intended position and the tool withdrawn.

Preferably the implant further comprises retrieval means. This is advantageous as it allows the

implant to be removed after a period of time and allows control over the length of time a drug is delivered. Further, it means the delivery device is not required to be retained in the body forever.

Preferably the retrieval means is adapted to allow the implant to be removed from the myometrium or the prostate after use.

The retrieval means can be any means which allows the removal of the implant from the myometrium or the prostate following a determined period of time. This provides a means for controlling the length of time over which the drug is delivered.

Preferably, the retrieval means comprises a hook at a proximal end of the implant.

Preferably, the body is generally J or U shaped such that the proximal end of the implant forms a loop or hook.

Alternatively the retrieval means comprises an elongate flexible member.

Preferably the elongate flexible member is a thin length of cord, twine or fibre.

Preferably the elongate flexible member is string.

Preferably the elongate flexible member can be left outside the myometrium and soft tissue surrounding

the uterus and / or vaginal cavity without causing irritation to a patient.

When it is desired to remove the implant, the flexible member can be manipulated to pull the implant out of the myometrium.

Alternatively the retrieval means is capable of accepting a screwdriver or other means for placing the implant in the body and/or removing the implant from the body.

Preferably the retrieval means can receive an implant removal device.

Preferably the medium may be any suitable substance for carrying a drug to be administered and slowly releasing it into the myometrium or the prostate, surrounding soft tissues and blood vessels.

Preferably the implant comprises a visible or palpable locator. This is advantageous as it allows the location of the implant to be determined by either a visual inspection or by a physical inspection.

More preferably the retrieval means is a visible or palpable locator.

This is advantageous as the retrieval means is typically accessible and would allow the location of

the implant to be checked by visual or physical inspection.

Preferably the implant may be left in the myometrium or the prostate for a prolonged length of time.

Preferably the implant may be left in the myometrium or the prostate and the drug delivered over a period of one month to 5 years.

The implant may be left in the myometrium or the prostate and the drug delivered over a period of at least one hour, 1 day, 1 to 3 months, 1 to 6 months, 1 to 12 months, 1 to 2 years or 1 to 5 years.

Preferably the medium for carrying the drug is any suitable pharmacological medium known in the art.

More preferably the medium for carrying the drug is a hydrogel, silicone based compound or elastomer.

Preferably the drug to be delivered cannot be taken orally.

Preferably the drug to be delivered promotes a contraceptive effect.

Preferably the drug to be delivered is a steroid.

More preferably the drug to be delivered is a hormone, for example progestagen.

Preferably the drug to be delivered is levonorgestrel or etonorgestrel for the provision of a contraceptive effect.

Alternatively, the drug to be delivered is at least one hormone for hormone replacement therapy (HRT).

It can be appreciated that a number of other drugs may be suitable for delivery by the invention such as agents for killing cancer cells or treating cancer, particularly cancer cells of the bladder, prostate or cervix or other pelvic malignancies. In these embodiments it is preferable that the drug to be delivered is cytotoxic.

Alternatively the delivery device can deliver one or more drug means suitable for radiotherapy.

The device may also be used to deliver one or more drugs for the treatment of an over active bladder, such drugs including anti-cholinergic drugs or calcium antagonists.

A drug delivered by the present invention may also include a microbicide. A microbicide is any agent detrimental to, or destructive of, the life of microbes, viruses or bacterial organisms. Such a microbicide could be used to destroy organisms responsible for sexually transmitted diseases such as gonorrhoea, chlamydia, genital herpes or HIV.

The drug delivery device and method of the present invention promotes smooth, controlled release of drugs to a specific site in the body, which allows absorption of drugs without subjecting drugs to liver metabolism.

Embodiments of the present invention will now be described by way of example only with reference to the accompanying drawings, in which:

Figure 1 is an illustration of a first drug delivery device according to the invention;

Figure 2 is an illustration of the drug delivery device of Figure 1 in use;

Figure 3 is a sectional view of the illustration in Figure 2 along the line A-A;

Figure 4 is an illustration of a second drug delivery device according to the invention;

Figures 5 and 6 are illustrations of further embodiments of a drug delivery device according to the present invention;

Figure 7 is a sectional view of the illustration in Figure 2 along line B-B; and

Figure 8 is an illustration of an embodiment of an implant of the present invention inserted in the prostate.

Referring to Figure 1, a drug delivery device comprises an implant 1 having a body 2 and a drug delivery means 3. The distal end of the body 2 has a point 4 for penetrating soft tissue and the proximal end of the body 2 is bent toward the distal end to provide a hook 5. The bent, curved portion or hook at the proximal end of the body 2 restricts the body 2 from becoming buried in soft tissue and allows retrieval of the implant 1 from soft tissue and the smooth muscle of the myometrium or the prostate.

The retrieval means provided by the hook 5 can both limit movement of the implant into the tissue and also provide means by which the location of the implant can be checked by visual or physical means.

The body is metallic and is typically constructed of surgical steel or titanium.

A portion of the body 2 between the point 4 and hook 5 houses the drug delivery means 3. In this example, a length of the body 2 between the point 4 and hook 5 has a reduced diameter relative to the diameter of the body 2 at the distal and proximal ends. The drug delivery means 3 comprises a cylinder of material formed around the reduced diameter portion of the body 2. In this example, the cylinder or material is a hydrogel carrying the drug to be delivered by the drug delivery device. In

another example, the material is a silicone based material or elastomer.

The body 2 has a diameter of 1mm and a length of 40mm. These diameters and lengths are, of course, for guidance only and other suitable dimensions will be apparent to those skilled in the art. For example depending of the amount of drug to be delivered the length of the body may be 20mm or 60mm.

Referring to Figure 2, the female human genital area comprises a bladder 6, urethra 7, vaginal cavity 8, cervix 9, uterus 10 and anus 11. In particular, the cervix 9, at a position between the vaginal cavity 8 and uterus 10, comprises the cervical canal 12 leading from the vaginal cavity 8 into the uterus 10 and surrounding smooth muscle known as the myometrium 13. The myometrium is defined by the serosa 20 (an epithelial layer of cells) and the endometrium 22. A sectional view of the cervix along line A-A is shown in Figure 3.

In use, the implant 1 is passed up the vaginal cavity 8 to the cervix 9 and inserted into the myometrium 13. The point 4 of the implant 1 facilitates easy insertion into the smooth muscle of the myometrium 13. The implant 1 may be manipulated using any suitable surgical tool during insertion, such as forceps or the like. No local anaesthetic is required as the myometrium has very few or no sensory nerves.

The drug delivery means is thus implanted into the myometrium 13. Surrounded by smooth muscle and soft tissue, the hydrogel located between the point 4 and the hook 5 slowly releases the drug it contains.

Depending of the release characteristics of the hydrogel and the chemical composition of the drug; release of the drug will typically occur between 1 month to 5 years from implantation.

During retention of the implant 1 in the myometrium 13, straightforward examination of the vaginal cavity 8 by a medical practitioner can verify that the implant 1 is in its intended position in the myometrium 13. Whilst there is little chance of the implant 1 becoming displaced, as the hook 5 remains outside the myometrium 13, any such displacement can be easily observed.

The location of the implant in the smooth muscle of the cervix and part of the body of the smooth muscle of the uterus of the myometrium allows the implant to be easily inserted and the location of the implant to be easily verified by routine examination.

Further, the implant is removable from the myometrium. The location of the implant in the tissue overcomes the disadvantages associated with vaginal rings and IUD coils such as discomfort,

particularly during intercourse, discharge and religious objections.

As smooth muscle of the cervix is highly vascularised and has little somatic innervation, drug delivery to these tissues show good pharmacokinetics and insertion of the implant is relatively painless for the patient.

Once the implant 1 has reached the end of its useful life, i.e. the drug has been administered for the intended length of time, the implant 1 can be removed by pulling on the hook 5 to withdraw the implant 1 from the myometrium 13. Again, this is a straightforward procedure without need for local anaesthetic.

Referring to Figure 4, in a second embodiment of the drug delivery device, an implant 14 comprises a rod 15 bent at a proximal end to form a hook 16. The hook 16 again allows easy retrieval of the implant 14 from the myometrium 13, along with enabling straightforward observation of the implant 14 during use. The rod 15 is made from plastics material impregnated with a drug to be delivered. The distal end 17 of the rod 15 is blunt.

In use, the implant 14 is inserted into the myometrium 13 in a similar way to the implant 1 of the first embodiment. However, as the rod 15 of the implant 14 has a blunt distal end 17, a needle-like delivery device (not shown) is used to insert the

implant 14 in the myometrium 13. The delivery device or tool more specifically comprises a sharp point for penetrating the smooth muscle of the myometrium 13 and attachment means for releasably attaching the implant 14 to the tool. The tool is driven into the myometrium 13 and the implant 14 released such that the tool can be withdrawn leaving the implant 14 in place.

Wherein the implant itself is the medium by which the drug to be administered is carried it can be envisaged that the drug delivery device is a hollow needle containing the implant and that the implant is injected into the myometrium 13. The use of implant comprising the medium of which the drug to be administrated is included, allows insertion of the implant into the myometrium 13 and delivery of the drug to be limited to a very short time scale.

The drug may be delivered to the myometrium 13 and be absorbed within a few minutes, hours, days or weeks depending on the medium. It can be appreciated that where the implant comprises the drug delivery medium, removal of the implant is not required. An absorbable implant therefore does not require retrieval means.

In another example, the implants 1, 14 may be provided with a string (not shown) attached to the proximal end of the implant 1, 14. This may be in addition to the hook 5, 16 or in place of the hook 5, 16. The string allows retrieval of the implant

1, 14 by pulling on the string and is useful particularly where the implant 1, 14 becomes buried in the soft tissue and smooth muscle of the myometrium 13.

Various improvements and modifications may be made without departing from the scope of the present invention. For example, it can be envisaged that the body of the implant may be formed from absorbable polymers. This would avoid the need to remove the implant at a later date. As shown in figure 5, the implant 25 can be corkscrew shaped. The implant can comprise retrieval means which includes a recess 26 capable of accepting a screwdriver (not shown) or other such means to allow the implant to be moved into and out of the tissue of the myometrium or prostate. In an alternative embodiment the implant can be a cylindrical mesh 30 (as shown in figure 6) which is able to be inserted into the myometrium or the prostate. An implant of cylindrical mesh shape would mean there would be an increased surface area of the implant in contact with the myometrium than would be present using a singular rod of similar dimensions. The amount of surface area of the implant in contact with surrounding tissue or muscle can influence the drug delivery characteristics of the implant. The implant as shown in figure 6 can be pushed into the myometrium or prostate and removed from the same using retrieval means 32. A tool (not shown) can be inserted into the retrieval means to allow removal of the implant.

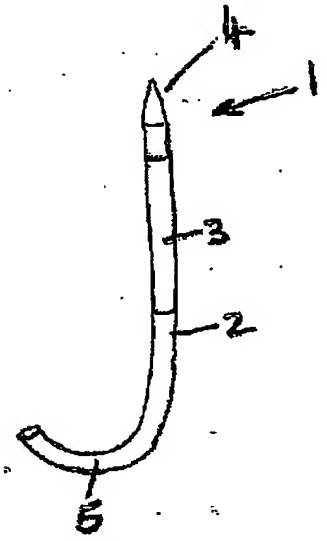

FIGURE 1

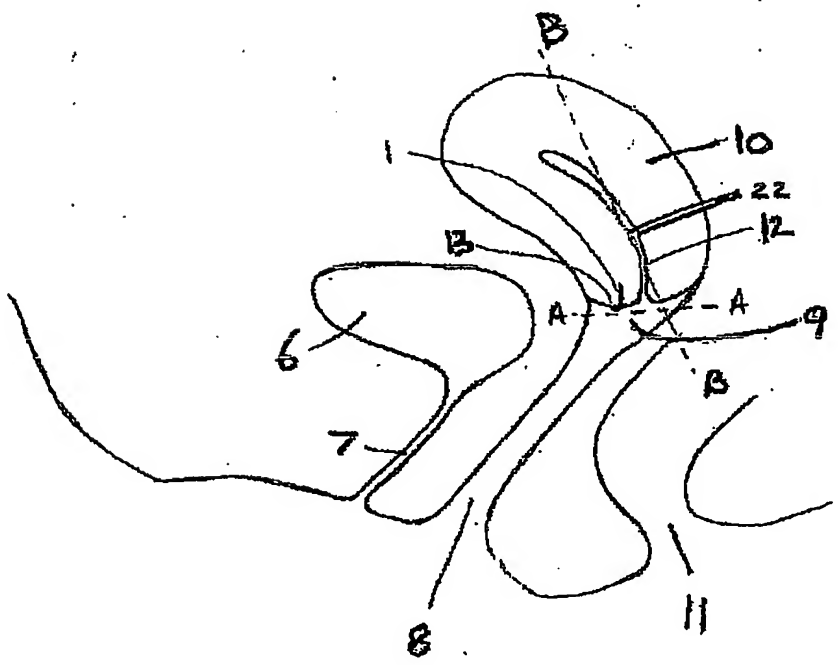

FIGURE 2

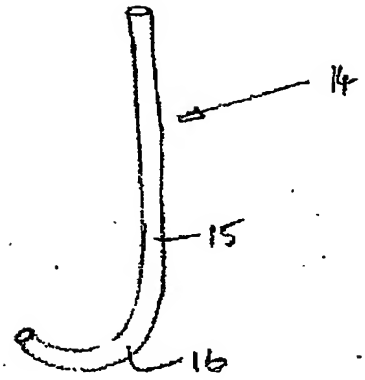

FIGURE 4

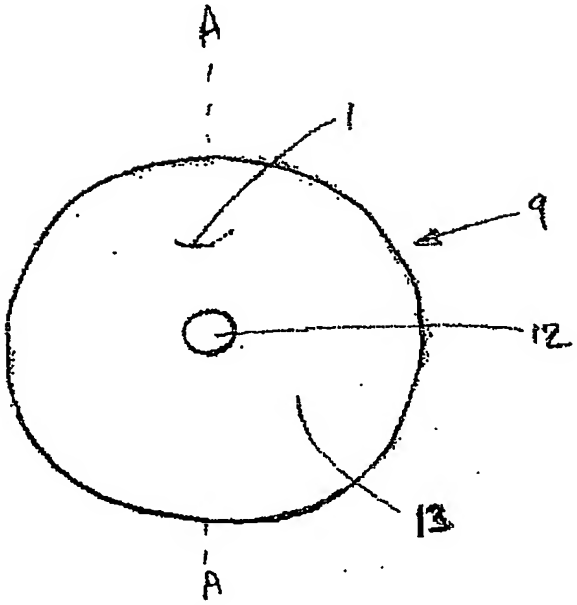

FIGURE 3

3/5

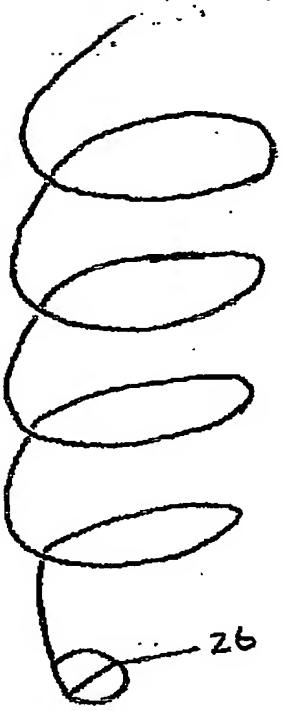

Figure 5.

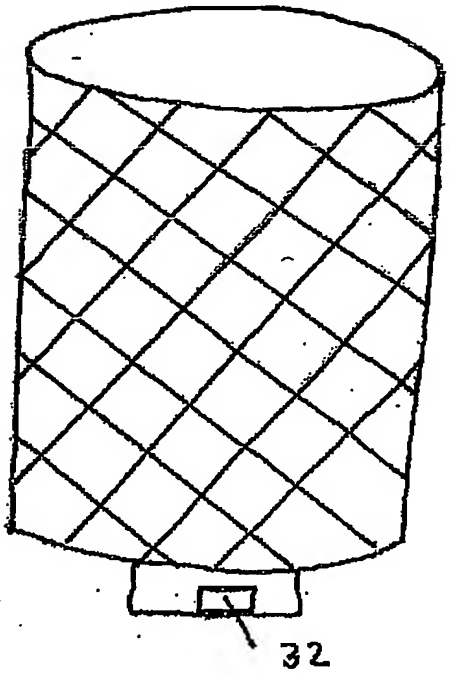

Figure 6

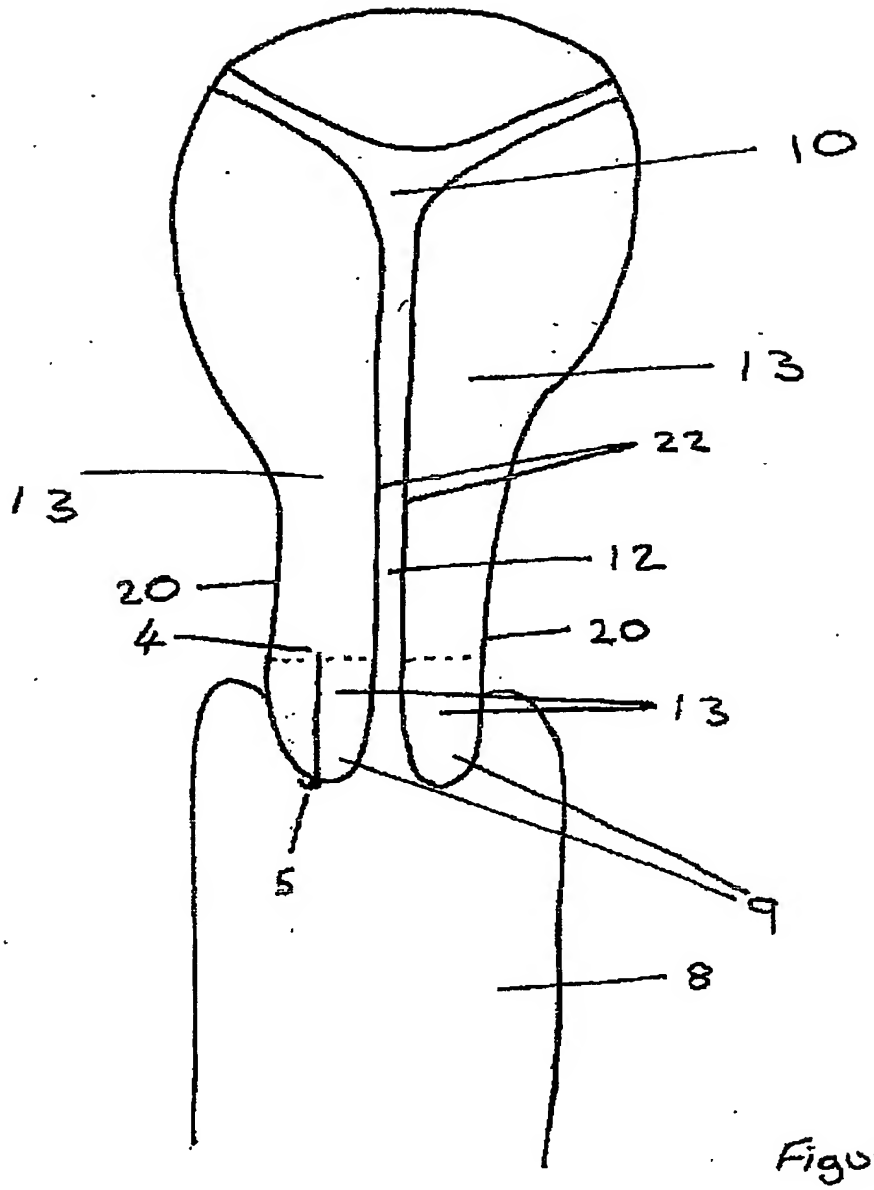

Figure 7

5/5

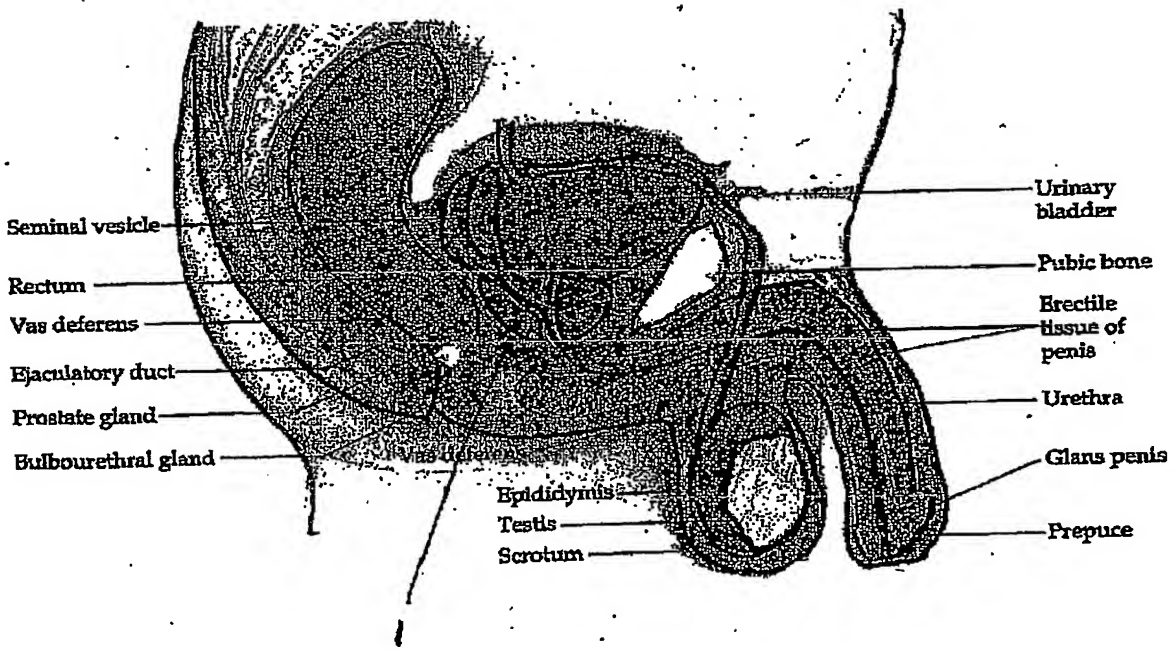
Seminal vesicle
Rectum
Vas deferens
Ejaculatory duct
Prostate gland
Bulbourethral gland
Epididymis
Testis
Scrotum
Urinary bladder
Pubic bone
Erectile tissue of penis
Urethra
Glans penis
Prepuce

Figure 8